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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,173	04/08/2004	Susan R. Webb	TSRI 536.1 C1	3667

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

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01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,173	WEBB ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-60,85-91,100-103 and 114-153* is/are pending in the application.

4a) Of the above claim(s) *34,37,38,41,85-91,100-103,114-140 and 151-153* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35,36,39,40,42-44,46,48,50,51,53,54,56,58 and 59* is/are rejected.

7)☒ Claim(s) *45,47,49,52,55,57,60 and 141-150* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/715,231, which is a divisional of U.S. Application Serial Number 09/194,285, which is a rule 371 continuation of PCT Serial Number PCT/US97/08697, which claims the benefit of the filing date of provisional U.S. Application 60/018,175.

Claims 1-32, 61-84, 92-99 and 104-113 have been canceled.

Claims 33-60, 85-91, 100-103 and 114-153 are currently pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 33-60 and 141-150, in the reply filed on February 16, 2007 is acknowledged.

Applicant's election without traverse of a "cell" as the species of matrix support in the reply filed on February 16, 2007 is acknowledged.

Applicant's election **with traverse** of a "costimulatory molecule," more specifically B7.1, as the species of accessory molecule in the reply filed on February 16, 2007 is acknowledged. Upon further review this particular species election requirement has been withdrawn.

1. Claims **85-91, 100-103, 114-140 and 151-153 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected invention**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2007.

Claims **34, 37, 38 and 41 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected species**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2007.

Accordingly, **claims 33, 35, 36, 39, 40, 42-60 and 141-150 are the subject of examination** in the present Office Action.

2. This application contains claims drawn to an invention non-elected without traverse in the reply filed on February 16, 2007. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

In view of Applicant's amendment and remarks filed September 24, 2007, only the following ground of rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33, 35, 36, 39, 40, 42-44, 46, 48, 50, 51, 53, 54, 56, 58, and 59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for accessory molecules selected from the costimulatory molecules B7.1 and B7.2, the adhesion molecules ICAM-1, ICAM-2, ICAM-3, LFA-1 and LFA-3 and the survival molecules Fas ligand, TNF receptor and CD70, does not reasonably provide enablement for other types of accessory molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It was previously stated: "Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are most broadly drawn to a "synthetic antigen presenting matrix" comprising the extracellular portion of Class II MHC molecule and an "accessory molecule." The instant specification discloses the accessory molecules B7.1, B7.2 (costimulatory molecules), ICAM-1, ICAM-2, ICAM-3, LFA-1, LFA-3 (adhesion molecules), Fas ligand, TNF receptor and CD70 (survival molecules). Beyond the disclosed elements, the term "accessory molecule" encompasses any molecule which may participate in the processes of antigen processing and/or presentation, including all molecules which have a role from capture and uptake of an antigenic molecule by the matrix to internal molecules (as the "matrix reads upon an intact cell) which chaperone the antigen or break up larger proteins into epitope peptides, molecules which assist the association of the epitope with the Class II molecule and cytokines which stimulate the activation of reactive T cells, as all such molecules perform accessory functions to MHC class II. The specification does not teach molecules which participate in all aspects of antigen processing and presentation and therefore does not provide sufficient guidance to one of ordinary skill in the art to practice the claimed invention commensurate in scope with the recitation of "accessory molecules."

Furthermore, a "teaching" in the specification of generic accessory molecules does not provide any information regarding the functionality of any of those generic molecules, nor does it provide any structural information to the artisan about the structural features of the generic molecules or how those generic molecules interact with the matrix/T cell interaction or with the antigen processing pathway. Exemplifying eight accessory molecules provides information only about those eight molecules and is not reasonably predictive of the artisan's success in incorporating other types of accessory molecules into the claimed synthetic matrix.

In view of the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and the statute does not sanction this.'

Applicant's arguments filed September 24, 2007 have been fully considered but they are not persuasive.

Applicant asserts that the full scope of the invention is enabled because the specification has exemplified eight different accessory molecules and because the specification "teaches" generic accessory molecules. This argument is not convincing, however. First of all, a "teaching" of generic accessory molecules does not provide any information regarding the functionality of any of those generic molecules, nor does it provide any structural information to the artisan about the structural features of the generic molecules or how those generic molecules interact with the APC/T cell interaction or with the antigen processing pathway. Exemplifying eight accessory molecules provides information only about those eight molecules and is not reasonably predictive of the artisan's success in incorporating other types of accessory molecules into the claimed artificial APCs. Applicant further argues that the specific accessory molecule to be used is not essential to the practice of the present invention. This is not convincing because the asserted utility of the claimed invention is to create a synthetic antigen presenting matrix that is capable of selectively activating CD4+ T cells into a particular T cell subset for producing a preferred cytokine profile. this directed activation is accomplished not only by the exposure of the T cell to antigen in the context of MHC class II, but is also determined by the exposure of the T cell to specific accessory molecules present on the matrix. Accordingly, the type of accessory molecule present on the matrix is a vital part of the claimed invention, not an irrelevant side note.

Conclusion

4. Claims 45, 47, 49, 52, 55, 57, 60 and 141-150 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
January 4, 2008

David A. Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER